FEB 2 3 2006

2901 simms street hollywood, florida 33020 tel 954.927.2044 fax 954.927.0446

EXHIBIT E - 510(K) SUMMARY

Submitter:	MAKO Surgical Corp.
Address:	2901 Simms Street, Hollywood, FL, 33020
Phone number / Fax Number:	(Ph) 954-927-2044 x105; (F) 954-927-0446
Contact Person:	William F. Tapia
Date Prepared:	December 30, 2005
Proprietary Name:	MAKO Surgical Unicondylar Knee System
Common Name:	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Classification Name / #:	Class II; 21 CFR 888.3520
Product Code:	87 HSX – Knee joint femorotibial metal/polymer non-constrained cemented prosthesis

Substantial Equivalence: The MAKO Surgical Unicondylar Knee System is substantially equivalent to Stelkast Corporation's Unicondylar Knee System (K032824).

Feature	Stelkast Unicondylar Knee System (K032824) / MAKO Surgical Corp.'s Unicondylar Knee System
Intended Use/Indications for Use	The MAKO Surgical Unicondylar Knee is a single use device intended for cemented reconstruction of the medial or lateral femur and corresponding tibial surface of moderately disabled and/or painful knee resulting from osteoarthritis, traumatic arthritis provided there is evidence of sufficient bone to seat the implant. Indications for use include moderate joint impairment from painful arthritis (osteo and/or post-traumatic), and as an alternative to tibial osteotomy in patients with unicompartmental arthritis.
Implant Components	o CoCr femoral component. o UHMWPE tibial component. o Radiographic marker pin in tibial component
Sizes	o Femoral components available in 5 sizes (left and right component for each size). o Tibial components available in 5 sizes with 3 thicknesses (6.5mm, 7.5mm, 8.5mm). Thinnest section of 6.5mm tibial component is 6.0mm.
Congruency	20 – 27% congruency
Materials	o Femoral component – CoCr per ASTM F-75 o Tibial component – UHMWPE per ASTM F-648 Type 2. o Radiographic marker pin – titanium wire per ASTM F-1341.
Instrumentation	Provided separately in a re-usable/sterilizable tray. Tray includes various tools (e.g., sizers, templates, trials, drill, gage, impactors, inserters, extractors) used during surgery.
Sterilization and Packaging	Sterilization: o Implant and tibial components – gamma radiation o Instrumentation – prevacuum steam Packaging: o Both femoral and tibial components are supplied in double sealed containers maintaining double sterile barriers. Tibial component is packaged in Argon gas environment.
Biocompatibility	Both devices are made of materials for surgical implant applications per ASTM standards listed above.

Description: The MAKO Surgical Unicondylar Knee System is for use in reconstruction of either the medial or lateral condyle and corresponding tibial surface. The MAKO Surgical Unicondylar Knee System consists of the following basic components. These components are intended for cemented, one-time use.

- CoCr distal femoral component

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- UHMWPE tibial resurfacing component – includes radiographic pin

Standard unicondylar knee instrumentation is also provided with the system. This includes for example femoral sizers, femoral templates with handles & peg drill assembly, tibial implant gage, tibial leveling guide, impactor, inserter, distractors, and extractors. These are provided separately in a reusable/sterilizable instrument tray.

Intended Use/Indications for Use: The MAKO Surgical Unicondylar Knee is a single use device intended for cemented reconstruction of the medial or lateral femur and corresponding tibial surface of moderately disabled and/or painful knee resulting from osteoarthritis, traumatic arthritis provided there is evidence of sufficient bone to seat the implant. Indications for use include moderate joint impairment from painful arthritis (osteo and/or post-traumatic), and as an alternative to tibial osteotomy in patients with unicompartmental arthritis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2006

Mr. William F. Tapia
Director of Regulatory/Quality/Clinical Affairs
Mako Surgical Corp.
2901 Simms Street
Hollywood, California 33020

Re: K060017
Trade/Device Name: Unicondylar Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: II
Product Codes: HSX
Dated: February 14, 2006
Received: February 15, 2006

Dear Mr. Tapia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

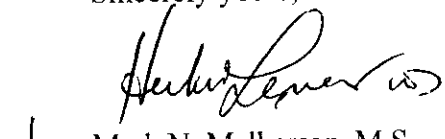
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson, M.S.
Acting Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

MAKO
SURGICAL CORP

EXHIBIT G

INDICATIONS FOR USE

510(k) Number (if known): K060017

Device Name: MAKO Surgical Unicondylar Knee System

Indications for Use:

The MAKO Surgical Unicondylar Knee is a single use device intended for cemented reconstruction of the medial or lateral femur and corresponding tibial surface of moderately disabled and/or painful knee resulting from osteoarthritis, traumatic arthritis provided there is evidence of sufficient bone to seat the implant. Indications for use include moderate joint impairment from painful arthritis (osteo and/or post-traumatic), and as an alternative to tibial osteotomy in patients with unicompartmental arthritis.

Prescription Use ___X____ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number_____